Glass-ionomer-based materials for preventing carious lesions in Chinese children

No registrations found.

Ethical review	Positive opinion
Status	Recruitment stopped
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON27411

Source
NTR

Brief title
N/A

Health condition

dental caries; carious lesion development; caries prevention; sealants.

Sponsors and support

Primary sponsor: initiator
Source(s) of monetary or material Support: finances received from
- KNAW, the Netherlands;
- College of Dental Sciences, the Netherlands;
-School of Stomatology, Wuhan, China.
Material support received from 3MESPE, China

Intervention

Outcome measures

Primary outcome

- Prevention of carious lesions in first permanent molars

Secondary outcome

1. Retention of the sealants

2. Costing of sealant application

3. Attrition pattern of sealants over time

4. Composition of sealants over time

Study description

Background summary

The study inclusion criteria consist of molar teeth in the mandible that are at high risk for developing carious lesions in pits and fissures of occlusal and buccal tooth surfaces of young children. The number of children included in the study have been determined through power calculations and randomly divided over 3 parallel groups: a resin, a high-viscosity glass-ionomer and a glass-carbomer sealant group. The different sealant materials have been applied using the manufacturers' Direction for Use.

Sealants will be periodically (0.5, 1, 2, 3, 4 and 5 years) evaluated by independent and calibrated evaluators using the ART criteria.
The wear pattern over time will be assessed from replicas produced from impressions taken at each of the 6 evaluation times. The measurements will include loss of volume and height obtained through using 3-D laser images and relevant computer software. Survival analysis and parametric tests will be applied to assess the type of sealant that prevents carious lesion development in pits and fissures of these children best. Cost data have been collected using activity sampling procedure.

Study objective

There is no difference in carious lesion development between sealants of glass-ionomer, glass-carbomer and composite resin and placed in first permanent molars after 5 years

Study design

Clinical evaluation after 6 months, 1, 2, 3, 4, and 5 years.

Each time of evaluation an impression of a sample of sealed teeth by group will be taken.

Intervention

Four sealant groups.

1. Composite resin = positive control

2. Glass-ionomer, improved version = experimental

3. Glass-ionomer plus light-curing = experimental

4. Glass-carbomer, new material = experimental

First permanent molars will be sealed.

Contacts

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Eligibility criteria

Inclusion criteria

1. Healthy children with at least 2 cavitated teeth in primary dentition and patent pits and fissures or presence of enamel carious lesion in first permanent molar (high caries risk group)

Exclusion criteria

1. Healthy children with less than 2 cavitated teeth in their primary dentition, and those with two or more cavitated primary teeth but with shallow pits and fissures in the first permanent molars.

2. Permanent molars with cavities

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Active

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	07-04-2008
Enrollment:	400
Type:	Actual

Ethics review

Positive opinion

Date:	10-09-2008
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL1382
NTR-old	NTR1441
Other	: 08CDP011
ISRCTN	ISRCTN wordt niet meer aangevraagd

Study results

Summary results
N/A